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510(k) SUMMARY: MICROSURGE THORACOSCOPIC SCISSORS

- (1) Microsurge, Inc.
150 A Street
Needham, MA 02194
(617)444-2300

Contact Person: Richard Lariviere
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- (2) Trade or Proprietary Name: Detachatip™ Thoracoscopic Scissors
- Common Name: Endoscopic Accessory, Manual Surgical Instruments
- Classified Name(s): Endoscope and/or Accessories (78KOG)
21 CFR § 876.1500, Class II,
Endoscope and Accessories
- (3) Predicates: Microsurge Detachatip Surgical Instruments
Karl Storz Thoracoscopic Scissors
Surgical Technologies International, Inc., Thoracoscopic Scissors
- (4) Description of Device: The Microsurge Thoracoscopic Scissors are a modular line of reusable surgical scissors consisting of various size scissors shafts and tips. These integral shafts and tips are essentially identical to the scissors shafts of the Microsurge Detachatip Surgical Instruments and are intended to be used in conjunction with the handles that have been cleared for marketing as part of the Microsurge Detachatip Surgical Instruments

The scissors tips and shafts are sized to fit through 5 mm cannula or directly through intercostal incisions. The shafts range in length from 24 to 43 cm, consistent with other endoscopic instruments such as the Detachatip line manufactured by Microsurge. The shafts are provided either straight or with a prefabricated reverse "S" shaped curve. The curve provides for increased range of motion when rotating the instrument, thus improving access to internal structures during endoscopic procedures. The shafts are also equipped with a cleaning port to enhance cleaning via direct delivery of cleaning solutions to the lumen of the instruments.

The scissors tips are provided in a variety of styles: curved (Metzenbaum), straight, and hook. Each style is suited for specific surgical requirements and tissue types.

53

- (5) **Intended Use:** The Microsurge Thoracoscopic Scissors are a line of reusable general surgical scissors intended to be used to cut, dissect and manipulate tissues during general open and thoracoscopic procedures.
- (6) **Technological Characteristics:** The Microsurge Thoracoscopic Scissors have the same technological characteristics as the predicate devices. The devices are reusable devices intended to cut, dissect and manipulate tissue through manual cycling of the handle finger and thumb loops
- (7) **Conclusion**

The new device has the same intended uses and technology as the predicates identified in the premarket notification submission. The Microsurge Thoracoscopic Scissors are at least as safe and effective as the predicate devices based on the device being in conformance with well-established biocompatibility standards and a rigorous, company-devised test simulating the device's anticipated field use to evaluate its durability.